


## You are the Key to HPV Cancer Prevention

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**YOU ARE THE KEY TO  
CANCER PREVENTION**

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### Objectives

1. Describe why HPV vaccination is important for cancer prevention.
2. Identify the appropriate HPV vaccination schedule based on patient age.
3. Describe effective HPV vaccine recommendations for patients age 11 or 12 years, as well as for age 13 years and older, including the new adult recommendations.
4. Develop self-efficacy in delivering effective HPV vaccination recommendations
5. Identify reassuring, confident, and concise responses to parental questions about HPV vaccination.



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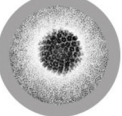
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## HPV

(Human papillomavirus)

Understanding the Burden

### HPV INFECTION & DISEASE



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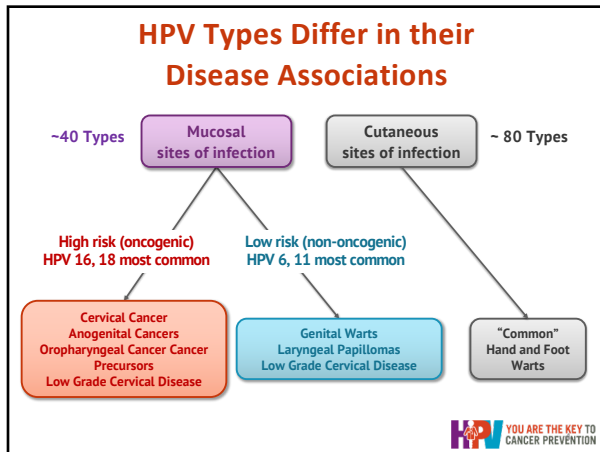
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**HPV Infection**

- Most females and males will be infected with at least one type of mucosal HPV at some point in their lives
  - Estimated 79 million Americans currently infected
  - 14 million new infections/year in the US
  - HPV infection is most common in people in their teens and early 20s
- Most people will never know that they have been infected

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Satterwhite et al. Sex Transm Dis. 2013

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**Cancers Caused by HPV per Year, U.S., 2012-2016**

Cancer site	Percentage probably caused by any HPV type	Number probably caused by any HPV type		
		Female	Male	Both Sexes
Cervix	91%	12,015	0	12,015
Vagina	75%	862	0	862
Vulva	69%	4,009	0	4,009
Penis	63%	0	1,303	1,303
Anus	91%	4,359	2,270	6,629
Oropharynx	70%	3,460	15,540	19,000
<b>TOTAL</b>		<b>24,705</b>	<b>19,113</b>	<b>43,818</b>

Based on <https://www.cdc.gov/cancer/uscs/about/data-briefs/no10-hpv-asso-cancers-UnitedStates-2012-2016.htm>

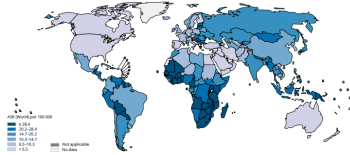
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## Cervical Cancer

- Cervical cancer is the most common HPV-associated cancer among women

- 569,847 new cases and 311,365 deaths world-wide in 2018
- Estimated 13,800 new cases and 4,290 deaths in the U.S. in 2020



- Half of cervical cancers occur in women <50 years

- A quarter of cervical cancers occur in women 25-39 years

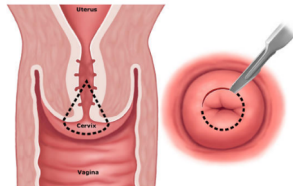
<https://ncod.cdc.gov/vncv/> and <http://gco.iarc.fr/today/home>



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## Cervical pre-cancer in U.S. females

- 1.4 million new cases of low grade cervical dysplasia
- 330,000 new cases of high grade cervical dysplasia



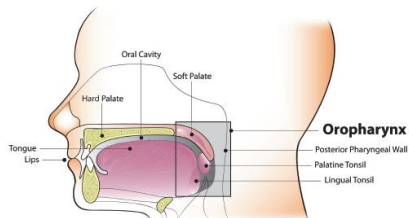
Koschil Sex Transm Dis. 2004.  
Schiffman Arch Pathol Lab Med. 2003.



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## Oropharyngeal Cancer

- 70% are HPV-associated
- 13,500 cases annually in the U.S.



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**HPV vaccine is cancer prevention.**

Talk to the doctor about vaccinating your 11–12 year old sons and daughters against HPV.

#UCanStopHPV

Evidence-Based HPV Disease Prevention

**HPV VACCINE**

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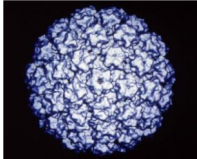
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**HPV Vaccines**

- Recombinant L1 capsid proteins that form “virus-like” particles (VLP)
- Non-infectious and non-oncogenic
- Produce higher levels of neutralizing antibody than natural infection



HPV Virus-Like Particle

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**HPV Vaccine Comparison**


HPV Types Included in Vaccine

	6	11	16	18	31	33	45	52	58
Bivalent									
Quadrivalent									
9-valent									

Genital warts

63% of cancers in body parts where HPV DNA is often found

10% of cancers in body parts where HPV DNA is often found

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Adapted from Petrosky et al. MMWR, 2015.

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## HPV Vaccine Recommendation

**CDC recommends routine vaccination at age 11 or 12 years to prevent HPV cancers**

- The vaccination series can be started at age 9 years
- Two doses of vaccine are recommended
- The second dose of the vaccine should be administered 6 to 12 months after the first dose.

Meites et al. MMWR. 2016.



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## HPV Vaccine Recommendations: Catch Up/Late

- Vaccination for all persons through age 26 years who were not previously adequately vaccinated.

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## HPV Vaccine Recommendations: Adults 27-45 years

- In June 2019, HPV vaccine was recommended for adults 27-45 years based on shared clinical decision making who have not been adequately vaccinated previously
- This recommendation are used in the context of a clinician-patient conversation to determine if vaccination may be appropriate for that patient

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### Dosing Schedules

**Starting the vaccine series before the 15th birthday**

**Recommended schedule is 2 doses of HPV vaccine**

- Second dose should be administered 6–12 months after the first dose (0, 6–12 month schedule)
- Minimum interval between dose one and dose two in a 2-dose schedule is 5 months


**Starting the vaccine series on or after the 15th birthday\***

**Recommended schedule is 3 doses of HPV vaccine**

- Second dose should be administered 1–2 months after the first dose, and the third dose should be administered 6 months after the first dose (0, 1–2, 6 month schedule)
- Minimum interval between dose one and dose three in a 3-dose schedule is 5 months

\*and immunocompromised persons 9–26 years

Meites et al. MMWR, 2016.



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### HPV Vaccination is Recommended at Age 11 or 12 Years

**Girls & Boys can start HPV vaccination at age 9**

**Preteens should finish the HPV vaccine series before their 13<sup>th</sup> birthday**




Plus girls 13–26 years old who haven't started or finished HPV vaccine series



Plus boys 13–26 years old who haven't started or finished HPV vaccine series

Meites et al. MMWR, 2016.



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### HPV VACCINE SAFETY

Meites et al. MMWR, 2016.



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## United States Vaccine Safety System

System	Collaborators	Description
<b>Vaccine Adverse Event Reporting System (VAERS)</b>	CDC and FDA	Frontline spontaneous reporting system to detect potential vaccine safety issues
<b>Vaccine Safety Datalink (VSD)</b>	CDC and 9 Integrated Health Care Systems	Large linked database system used for active surveillance and research ~9.4 million members (~3% of US pop.)
<b>Clinical Immunization Safety Assessment (CISA) Project</b>	CDC and 7 Academic Centers	Expert collaboration that conducts individual clinical vaccine safety assessments and clinical research
<b>Post-Licensure Rapid Immunization Safety Monitoring Program (PRISM)</b>	FDA and 6 partner organizations	Large distributed database system used for active surveillance and research ~170 million individuals



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## Over 10 Years of HPV Vaccine Safety Data

- HPV vaccine is safe
- As of 2017, over 270 million doses have been distributed worldwide
- 100 million doses have been given in the U.S.
- Over 100 studies including 2.5 million people in 6 different countries have been completed
- No serious side effects reported

Gee, et al. Hum Vaccin Immunother. 2016.



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## Over 10 Years of HPV Vaccine Safety Data

- HPV vaccine is safe
- Reactions after vaccination may include
  - Injection site reactions: pain, redness, and/or swelling in the arm where the shot was given
  - Systemic: fever, headaches
- HPV vaccines should not be given to anyone who has had a previous allergic reaction to the vaccine or who has an allergy to yeast (Gardasil/Gardasil 9)
- Brief fainting spells (syncope) and related symptoms (such as jerking movements) can happen soon after any injection, including HPV vaccine
- Patients should be seated (or lay down) during vaccination and remain in that position for 15 minutes

Gee, et al. Hum Vaccin Immunother. 2016.



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## HPV Vaccination is Safe

HPV vaccine safety studies have been very reassuring: HPV vaccine has a good safety profile

To date, we have not observed any signal that shows that HPV vaccination causes death, neurologic conditions, autoimmune conditions, or venous thromboembolism (VTE).

Clinicians can reassure parents who may have concerns, that HPV vaccination is safe.

<https://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-facts.html>



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Monitoring Impact of HPV Vaccine Programs on HPV-Associated Outcomes

## HPV VACCINE IMPACT



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## HPV vaccine impact monitoring

- Post licensure evaluations are important to evaluate real world effectiveness of vaccines
- Population impact against early and mid outcomes have been reported:

### HPV prevalence

- Australia, Norway, Denmark, Sweden, UK, US

### Genital warts

- Australia, New Zealand, Denmark, Sweden, Germany, Quebec, US

### Cervical lesions

- Australia, British Columbia, Denmark, Sweden, US



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## HPV vaccine impact in the U.S.

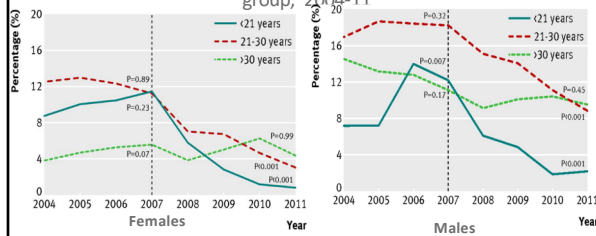
- Declines observed in:
  - Vaccine type prevalence
  - Genital warts
  - Cervical pre-cancers



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## Impact of HPV vaccination in Australia

Proportion of Australian born females and males diagnosed as having genital warts at first visit, by age group, 2004-11



Ali et al. BMJ. 2013



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## Systematic Review and Meta-Analysis: Population-Level Impact of HPV Vaccination

- Review of 20 studies in 9 high income countries
- In countries with **>50% coverage**, among 13-19 year olds
  - HPV 16/18 prevalence **decreased at least 68%**
  - Anogenital warts decreased by ~61%
- Evidence of herd effects
- Some evidence of cross protection against other types

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Drolet et al. Lancet Infect Dis. 2015




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### HPV Vaccine Duration of Protection

- Studies suggest that vaccine protection is long-lasting
- No evidence of waning protection
  - Available evidence indicates protection for *at least* 10 years
  - Multiple studies are in progress to monitor

ACIP, Summary Report, June 22-23, 2016.



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### HPV Vaccination Is Safe, Effective, and Provides Lasting Protection

**HPV Vaccine is SAFE**


- Benefits far outweigh any potential risks
- Safety studies findings for HPV vaccination are reassuring and similar to MenACWY and Tdap vaccine safety reviews

**HPV Vaccine WORKS**

- Population impact against early and mid outcomes have been reported in multiple countries

**HPV Vaccine Protection LASTS**

- Studies suggest that vaccine protection is long-lasting
- No evidence of waning protection



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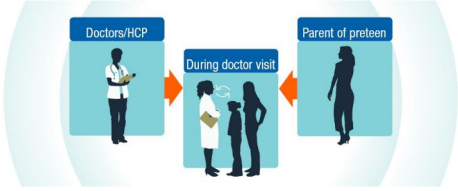
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Talking about HPV vaccine

### FRAMING THE CONVERSATION



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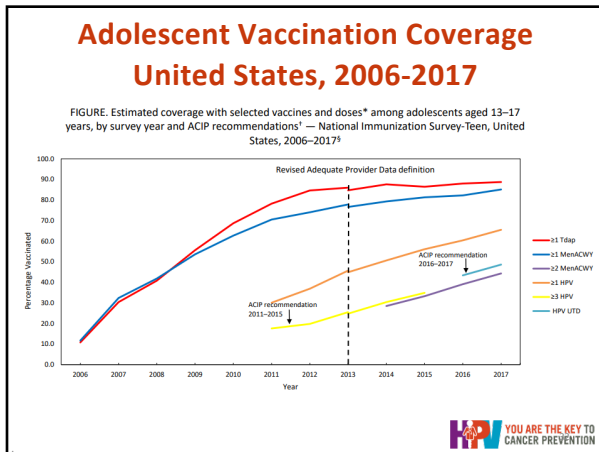
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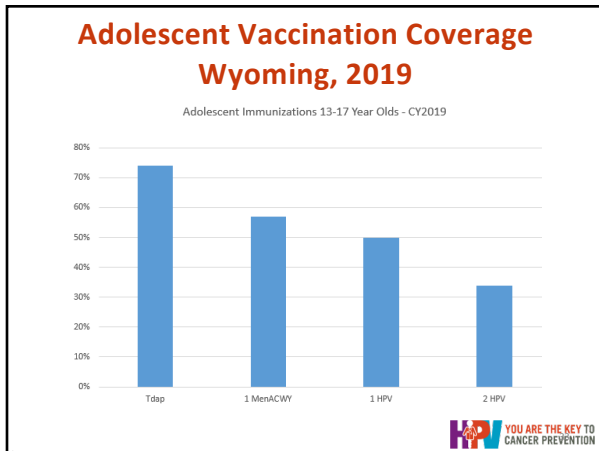
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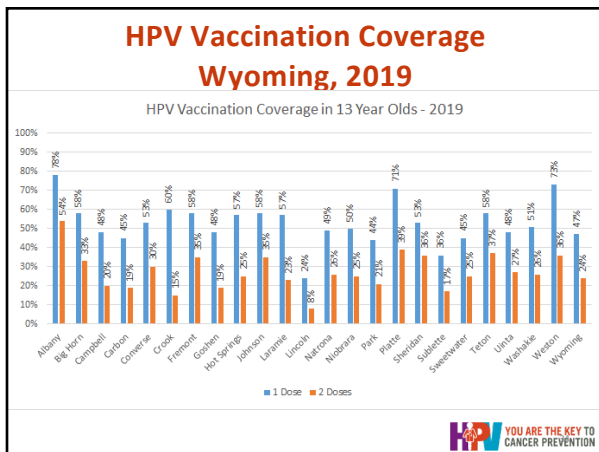
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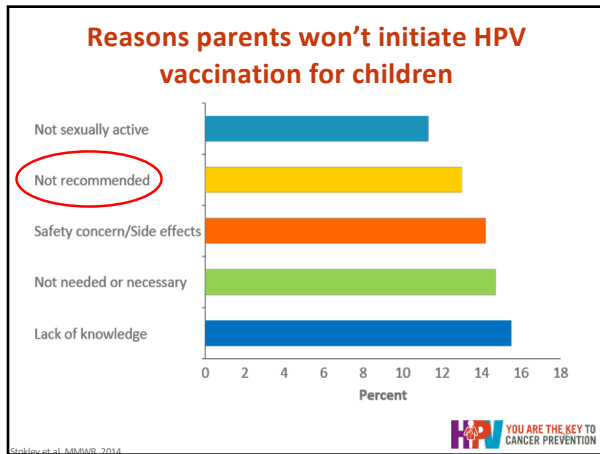
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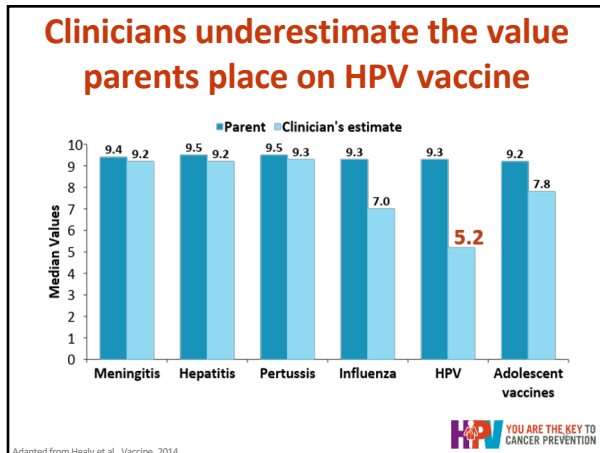
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**“The perceived and real concerns of parents influence how the clinician recommends and administers HPV vaccine.”**

Adapted from Healy et al. Vaccine 2014

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### Give an Effective Recommendation to Receive HPV Vaccine at Ages 11 or 12

- *An effective recommendation from you is the main reason parents decide to vaccinate*
- Many moms in focus groups stated that they trust their child's doctor and would get the vaccine for their child as long as they received a recommendation from the doctor

Smith et al. Vaccine. 2016. Unpublished CDC data, 2013.



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What is an  
**EFFECTIVE**  
recommendation  
for HPV vaccination?



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Same Way  
Same Day



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### Make an Effective Recommendation

- **Same way:** Effective recommendations group all of the adolescent vaccines  
Recommend HPV vaccination the **same way** you recommend Tdap & meningococcal vaccines.
- **Same day:** Recommend HPV vaccine **today**  
Recommend HPV vaccination the **same day** you recommend Tdap & meningococcal vaccines.

Brewer et al. Pediatrics. 2017. Unpublished CDC data, 2013.



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*Your preteen  
needs three vaccines **today**  
to protect against  
**meningitis,**  
**HPV cancers,**  
and **pertussis.***

Brewer et al. Pediatrics. 2017.



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Now that Josh is 11, he is due for three vaccines today. These will help protect him from the infections that can cause meningitis, HPV cancers, and pertussis. We'll give those shots at the end of the visit.



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Now that Josh is 11, he is due **today** for three important vaccines. **The first is to help prevent an infection that can cause meningitis, which is very rare, but potentially deadly.** **The second is to prevent a very common infection, HPV, that can cause several kinds of cancer.** **The third is the “tetanus booster” which also protects against pertussis, so your child doesn’t get whooping cough, but also to protect babies too young to be vaccinated.** We’ll give those shots at the end of the visit. Do you have any questions for me?



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### Some Parents Need Reassurance

- Many parents simply accept this bundled recommendation
- Some parents may be interested in vaccinating, yet still have questions. Interpret a question as **they need additional reassurance from YOU, the clinician they trust with their child’s health care**
- Ask parents about their main concern (be sure you are addressing their real concern)
- Questions/concerns do not always equal hesitancy or refusal!

Unpublished CDC data, 2013


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### *Why does my child need HPV vaccine?*



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HPV vaccination is important  
because it prevents cancer.  
That's why I'm recommending that  
your child start the HPV vaccine  
series today.



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***What cancers are caused by  
HPV infection?***



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Certain HPV types can cause cancer of the  
cervix, vagina, and vulva in females, cancer of  
the penis in men, and in both females and  
males, cancers of the anus and the throat.  
We can help prevent infection with the HPV  
types that cause these cancers by starting the  
HPV vaccine series today.



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*Is my child really at risk for  
HPV?*



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HPV is a very common and  
widespread virus that infects both  
females and males. We can help  
protect your child from the cancers  
and diseases caused by the virus  
by starting HPV vaccination today.



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*Why at 11 or 12 years old?*



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### When should the bike helmet go on?



- A. Before they get on their bike
- B. When they are riding their bike in the street
- C. When they see the car heading directly at them
- D. After the car hits them



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### When do we put our seat belts on?

- A. Before turning on car
- B. When leaving driveway
- C. After a near accident



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As with all vaccine-preventable diseases, we want to protect your child early. If we start now, it's one less thing for you to worry about.

Also, your child will only need two shots of HPV vaccine at this age. If you wait until 15, your child will need three shots.

We'll give the first shot today and then you'll need to bring your child back in 6 to 12 months from now for the second shot.



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*I'm just worried that my child will perceive this as a green light to have S-E-X.*



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Numerous research studies have shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age.



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*“How long can we wait and still give just two doses?”*



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The two-dose schedule is recommended if the series is started before the 15th birthday. However, I don't recommend waiting to give this cancer-preventing vaccine. As children get older and have busier schedules, it becomes more difficult to get them back in. I'd feel best if we started the series today to get your child protected as soon as possible.




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***I have some concerns about the safety of the vaccine—I keep reading things online that says HPV vaccination isn't safe. Do you really know if it's safe?***




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It sounds like you are generally in support of vaccines, but you have concerns about the safety of HPV. Is that right?

So if you had information that convinced you the HPV vaccine was safe you might consider letting your daughter get it?

I'd like to share with you what I know about the safety of HPV vaccine...




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I know there are stories in the media and online about vaccines, and I can see how that could concern you.

However, I want you to know that HPV vaccine has been carefully studied for many years by medical and scientific experts.

Based on all of the data, I believe HPV vaccine is very safe.



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Vaccines, like any medication, can cause side effects. With HPV vaccination this could include pain, swelling, and/or redness where the shot is given, or possibly headache.

Sometimes kids faint when they get shots and they could be injured if they fall from fainting.

We'll protect your child by having them stay seated after the shot.



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***Could HPV vaccine cause my child to have problems with... ?***



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There is no data available to suggest that HPV vaccine will affect future fertility. However, women who develop cervical cancer could require treatment that would limit their ability to have children. Starting the HPV vaccine series today could prevent that from happening and protect your daughter's ability to bear children.



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More than a decade of HPV vaccine safety studies have been very reassuring. To date, we have not observed any signal that shows that HPV vaccination causes death/ neurologic conditions/ autoimmune conditions/ venous thromboembolism/ postural orthostatic tachycardia syndrome/ complex regional pain syndrome.



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***How do you know if the vaccine works?***



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Ongoing studies continue to show that HPV vaccination works very well.

HPV infections, genital warts, and cervical precancers in young people have all decreased in the years since the vaccine has been available.



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***Why do boys need HPV vaccine?***



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HPV infection can cause cancers of the penis, anus, and throat in men.

HPV infection can also cause genital warts.



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***We only want the vaccines  
needed for school.***



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All three vaccines are strongly and  
equally recommended by the CDC.  
All three are also recommended by  
Pediatric, Adolescent, and Family  
Medicine doctors and groups.  
School-entry requirements don't always  
reflect the current recommendations  
for your child's health.



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***Would you get HPV vaccine  
for your kids?***



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Yes, I have given HPV vaccine to my child. I believe strongly in the importance of this cancer-preventing vaccine.



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***I heard there is a new HPV vaccine that works better. Should I be getting that for my child who already was vaccinated?***



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Currently there is no recommendation for additional vaccination for someone who has already completed an HPV vaccine series.

All HPV vaccines protect against the infections that cause most of the cancers.



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### If a parent doesn't say yes today...

Ask	<ul style="list-style-type: none"> <li>Clarify &amp; restate their concerns to make sure you understand</li> </ul>
Acknowledge	<ul style="list-style-type: none"> <li>Emphasize it is the parents' decision</li> <li>Acknowledge risks &amp; conflicting info sources</li> <li>Applaud them for wanting what is best for their child</li> <li>Be clear that you are concerned for the health of their child, not just public health safety</li> </ul>
Advise	<ul style="list-style-type: none"> <li>Allow time to discuss the pros &amp; cons of the vaccine</li> <li>Be willing to discuss parents' ideas</li> <li>Offer written resources for parents</li> <li>Tailor your advice using this presentation</li> </ul>

Adapted from Eisenbergson New Brunswick 2014



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### If a parent declines today...

- Declination is not final. The conversation can be revisited.
- End the conversation with at least 1 action you both agree on.
- Because waiting to vaccinate is the risky choice, many pediatricians ask the parent to sign a Declination Form.



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### Ensure ALL your patients are protected

- Align office/clinic policy with mission
  - Immunize at every opportunity
  - Implement and utilize standing orders
  - Prompt staff to assess and administer the vaccine
  - Recommend the same day, the same way
  - Reminder recall
  - Know your clinic's coverage rates



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### Paying for HPV Vaccine

- Section 2713 of the Public Health Service Act requires non-grandfathered commercial health plans and state Medicaid expansion programs to cover all ACIP recommended vaccines without cost sharing



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### Paying for HPV Vaccine

- Available through the Vaccines for Children (VFC) program for patients 18 years and younger
- Not available through WyVIP and Vaccines for Uninsured Adults (VUA) programs
- Merck Patient Assistance Program:  
<https://www.merckhelps.com/gardasil%209>



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## HPV VACCINE IS CANCER PREVENTION

*And YOU are the key!*

Heidi Gurov, RN  
heidi.gurov@wyo.gov  
307-777-8981



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